

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Boschetti	Confirmation No.:	1038
Application. No.:	10/692,785	Art Unit:	1618
Filed:	October 27, 2003	Examiner:	JONES, Dameron Levest
For:	POLYVINYL ALCOHOL MICROSPHERES AND INJECTABLE SOLUTIONS OF THE SAME	Attorney Docket No.:	9676-314-999 (CAM: 405916-999056)

**REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)**

MAIL STOP: ISSUE FEE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants received a Notice of Allowance mailed September 29, 2008, from the United States Patent and Trademark Office ("PTO") in connection with Application No. 10/692,785 (hereinafter "the '785 application"), together with a Determination of Patent Term Adjustment under 35 U.S.C. §154(b) stating that the projected patent term adjustment to date is 0 days.

Applicants hereby respectfully request reconsideration of the patent term adjustment indicated in the Determination of Patent Term Adjustment under 35 U.S.C. §154(b) ("Determination") mailed September 29, 2008. Specifically, Applicants believe that the patent term adjustment of 0 days is not correct. The correct number of days for the patent term adjustment, for reasons explained below, is instead believed to be **387** days. The factual and legal basis for this request is set forth below.

REMARKS

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(b) must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
 - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
 - (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
 - (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
 - (B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

See 37 C.F.R. § 1.705(b).

In support of this request, Applicants submit the fee and the following statement of facts and law:

1. Fee Required Under 37 C.F.R. § 1.705(b)(1)

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this application is believed to be **\$200.00** and will be paid by EFS-web.

Please charge any underpayment or credit any overpayment to Jones Day Deposit Account No. 50-3013 (Ref. No. 9676-314-999).

2. Statement Required Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.702, Applicants submit the following statement of facts in support of this application:

- (i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:

1. Correct patent term adjustment:

The correct patent term adjustment is **387** days, which is attributable to (a) the failure of the PTO to mail a notification under 35 U.S.C. § 132 not later than fourteen months after the date on which the '785 application was filed under 35 U.S.C. § 111(a) (a delay under 37 C.F.R. § 1.702(a)(1); "the A period"); and (b) the failure of the PTO to issue a patent within three years of the actual filing date of the '785 application (a delay under 37 C.F.R. § 1.702(b); the "B period").

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

- (a) PTO Delay under 37 C.F.R. § 1.702(a) - Failure to Take Specific Action Within Specified Time Frames (the "A Period")

The delay by the PTO under 37 C.F.R. § 1.702(a) is believed to be **184** days.

Pursuant to 37 C.F.R. § 1.703(a), the period of adjustment under § 1.702(a) (the “A period”) is equal to the number of days in the period beginning on the day after the date that is fourteen months after the date on which the application was filed and ending on the mailing of an action under 35 U.S.C. § 132.

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. §132 within fourteen months from the date of filing of the '785 application. *See* PTO's Patent Application Information Retrieval page for U.S. Application No. 10/692,785 at Patent Term Adjustment History (“PTO PAIR Adjustment,” Exhibit A). The '785 application was filed on October 27, 2003. The first notification under 35 U.S.C. §132 (a Restriction Requirement) was mailed by the PTO on June 29, 2005. Accordingly, the PTO did not mail a notification under 35 U.S.C. §132 (or a notice of allowance under 35 U.S.C. §151) within fourteen months after the date on which the application was filed (or by December 27, 2004), and thus, the delay under 37 C.F.R. § 1.702(a)(1) is believed to be 184 days.

(b) *PTO Delay under 37 C.F.R. § 1.702(b) - Failure to Issue a Patent Within Three Years of the Actual Filing Date of the Application (the “B period”)*

The delay by the PTO under 37 C.F.R. § 1.702(b) is believed to be 368 days.

Pursuant to 37 C.F.R. § 1.703(b), the period of adjustment under § 1.702(b) (the “B period”) is equal to the period beginning the day after the date that is three years after the date on which the application was filed and ending the date a patent was issued, but not including the sum of the number of days in the period beginning on the date on which a request for continued examination of the application was filed and ending on the date the patent was issued.

The '785 application was filed under on October 27, 2003. The PTO did not issue a patent within three years of the date on which the application was filed, *i.e.*, by October 27, 2006.

A Request for Continued Examination was filed on October 31, 2007. Thus, the entire period between October 31, 2007 and the issuance of the patent on the above-referenced patent application is excluded from Patent Term Adjustment calculations. See 37 C.F.R. § 1.702(b)(2).

Accordingly, Applicants submit that the period of delay in the B period is 368 days, which is the number of days between the three year anniversary of October 27, 2006 and the date of the filing of the Request for Continued Examination on October 31, 2007.

(c) Overlapping Days in the PTO Delay Periods

The period of overlap between the delay by the PTO under 37 C.F.R. §§ 1.702(a) and (b) is 0 days.

According to 35 U.S.C. § 154(b)(2)(A): “To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” See 35 U.S.C. § 154(b)(2)(A).

Applicants respectfully submit that under recent case law, calculating the patent term adjustment is the result of summing the number of days of delay under 37 C.F.R. § 1.702(a) that do not comprise actual calendar days occurring in the B period (that is, the A period minus calendar days overlapping in both the A and B periods) and the number of days of delay under 37 C.F.R. § 1.702(b) (the B period). See *Wyeth et al. v. Dudas*, 2008 WL 445642, 88 USPQ2d 1538 (D.D.C. 2008).

In *Wyeth*, the Court held that “the only way that periods of time can ‘overlap’ is if they occur on the same day [and thus, if] an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap.”

As discussed above, Applicants submit that there are zero (0) actual calendar days of the 184 days in the A period that were actual calendar days included in the 368 days of the B period.

- (ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) are as follows:

1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is “[t]he number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. § 111(a) and ending on the date of mailing of either an action under 35 U.S.C. § 132, or a notice of allowance under 35 U.S.C. § 151, whichever occurs first.”

The patent term adjustment calculated by the PTO correctly included the time period under 37 C.F.R. § 1.702(a)(1) for the period beginning December 27, 2004 (fourteen months after the date on which the ‘785 application was filed) and ending on June 29, 2005, the date the Restriction Requirement was mailed from the PTO. Applicants confirm this period consists of 184 days.

An adjustment is also sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that “the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a)...and ending on the date a patent was issued.” A Request for Continued Examination was filed on October 31, 2007. Thus, pursuant to 37 C.F.R. § 1.702(b)(2) and 37 C.F.R. § 1.703(b)(1), the entire period between October 31, 2007 and the issuance of the patent on the above-referenced patent application is excluded from Patent Term Adjustment calculations. However, an adjustment is sought under 37 C.F.R. § 1.703(b) of 368 days, which is the number of days between the three year anniversary of October 27, 2006 and the date of the filing of the Request for Continued Examination on October 31, 2007.

Applicants further submit that the 184 actual calendar days of delay under 37 C.F.R. § 1.702(a) do not overlap the any of the 368 actual calendar days of delay under 37 C.F.R. § 1.702(b), as explained above.

Accordingly, Applicants' believe that the delays attributable to the PTO under 37 C.F.R. § 1.702 total 552 days, not 184 days as calculated by the PTO.

2. Adjustment under 37 C.F.R. § 1.703(f):

As discussed in sections (I) and (ii) above, Applicants believe that the total delay by the PTO amounts to 552 days under 37 C.F.R. § 1.702(a)(1) (*i.e.*, 184 days) and § 1.702(b) (*i.e.*, 368 days).

As discussed in Section (iv) below, Applicants further believe that the total delay attributable to Applicants is 165 days.

As such, Applicants believe that the total period of adjustment due under 37 C.F.R. § 1.703(f) is 387 days, which is the sum of the periods by the PTO calculated under 37 C.F.R. §§ 1.702(a) through (e) (*i.e.*, 552 days) to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704 (*i.e.*, 165 days).

(iii) The '785 application is not subject to a terminal disclaimer.

(iv) The circumstances during the prosecution of the '785 application that might constitute a failure to engage in reasonable efforts to conclude processing or examination of the '785 application as set forth in 37 C.F.R. § 1.704 are believed to consist of the following:

As acknowledged by the PTO in its calculation of the patent term adjustment, Applicants have a cumulative total of 165 days of Applicant delay through October 31, 2007 (RCE filing), which includes a total of 75 days of delay prior to October 27, 2006 (the 3 year anniversary) and

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a total of 90 days between October 27, 2006 and October 31, 2007. *See* PTO PAIR Adjustment, Exhibit A.¹

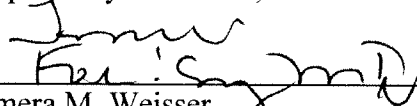
As such, Applicants believe that the delay by the Applicants under 37 C.F.R. § 1.704(a) is 165 days.

In summary, the total adjustment under 37 C.F.R. § 1.702(a) and (b) is 552 days, the total delays attributable to Applicants under 37 C.F.R. § 1.704 is 165 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 387 days. Accordingly, Applicants respectfully request an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling 387 days.

Applicants submit that the issues raised in this request for reconsideration of patent term adjustment are timely raised under 37 C.F.R. § 1.705(b), which provides in relevant part, that “[a]n application for patent term adjustment under this section *must be filed no later than the payment of the issue fee...*” (emphasis added); *e.g.*, three (3) months from the mailing of the Notice of Allowance. An Issue Fee Payment Authorization accompanies this Request, hence Applicants submit that the issues raised in this request are timely raised.

Date: December 29, 2008

Respectfully submitted,


Tamera M. Weisser 47,856 (Reg. No.)
For: Anthony M. Insogna (Reg. No. 35,203)

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¹ Applicants have a further 76 days after October 31, 2007, which includes 33 days of delay shown in the PTO PAIR Adjustment, plus an additional 43 days for the number of days between September 29, 2008 Notice of Allowance and November 10, 2008 Response to Amendment under § 1.312. However, because this delay is after the filing of an RCE on October 31, 2007, the entire period of which is excluded from calculation of patent term pursuant to 37 C.F.R. § 1.703(b), only delays occurring before October 31, 2007 are discussed herein with respect to the overall calculation of patent term.

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Patent Term Adjustment Under 37 C.F.R. § 1.705(b)
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Exhibit A

EXHIBIT A:
PTO PAIR Adjustment

10/692,785	POLYVINYL ALCOHOL MICROSPHERES,AND INJECTABLE SOLUTIONS OF THE SAME	12-29- 2008::16:12:54
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/692,785

Filing or 371(c) Date:	10-27-2003	USPTO Delay (PTO) Delay (days):	184
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	198
Post-Issue Petitions (days):	+0	Total PTA (days):	0
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
09-29-2008	Mail Notice of Allowance		
09-25-2008	Notice of Allowance Data Verification Completed		
09-25-2008	Case Docketed to Examiner in GAU		
09-25-2008	Document Verification		
09-25-2008	Examiner's Amendment Communication		
09-15-2008	Examiner Interview Summary Record (PTOL - 413)		
09-25-2008	Date Forwarded to Examiner		
09-15-2008	Response after Non-Final Action		
09-04-2008	Mail Non-Final Rejection		
09-02-2008	Non-Final Rejection		
05-27-2008	Information Disclosure Statement considered		
05-27-2008	Information Disclosure Statement (IDS) Filed		
06-26-2008	Date Forwarded to Examiner		
05-27-2008	Response after Non-Final Action		33
05-27-2008	Request for Extension of Time - Granted		↑
05-27-2008	Information Disclosure Statement (IDS) Filed		↑
01-24-2008	Mail Non-Final Rejection		↑
01-22-2008	Non-Final Rejection		
10-31-2007	Information Disclosure Statement considered		
10-31-2007	Information Disclosure Statement (IDS) Filed		
12-06-2007	Date Forwarded to Examiner		
12-06-2007	Date Forwarded to Examiner		
10-31-2007	Request for Continued Examination (RCE)		19
12-06-2007	DISPOSAL FOR A RCE/CPA/129 (express abandonment if CPA)		↑
10-31-2007	Request for Extension of Time - Granted		↑
10-31-2007	Information Disclosure Statement (IDS) Filed		↑
10-31-2007	Workflow - Request for RCE - Begin		↑
07-12-2007	Mail Final Rejection (PTOL - 326)		↑
07-09-2007	Final Rejection		
04-11-2007	Information Disclosure Statement considered		
11-07-2006	Information Disclosure Statement considered		
04-11-2007	Information Disclosure Statement (IDS) Filed		
04-11-2007	Information Disclosure Statement (IDS) Filed		

05-02-2007	Date Forwarded to Examiner	
04-11-2007	Response after Non-Final Action	71
04-11-2007	Request for Extension of Time - Granted	↑
11-21-2006	Mail Examiner Interview Summary (PTOL - 413)	↑
11-07-2006	Information Disclosure Statement (IDS) Filed	↑
11-07-2006	Information Disclosure Statement (IDS) Filed	↑
11-14-2006	Examiner Interview Summary Record (PTOL - 413)	↑
10-30-2006	Mail Non-Final Rejection	↑
10-27-2006	Non-Final Rejection	
10-12-2006	Correspondence Address Change	
10-13-2006	Change in Power of Attorney (May Include Associate POA)	
10-12-2006	Date Forwarded to Examiner	
10-02-2006	Amendment after Final Rejection	30
10-02-2006	Request for Extension of Time - Granted	↑
06-02-2006	Mail Final Rejection (PTOL - 326)	↑
05-30-2006	Final Rejection	
03-27-2006	Date Forwarded to Examiner	
03-16-2006	Response after Non-Final Action	28
03-16-2006	Request for Extension of Time - Granted	↑
11-16-2005	Mail Non-Final Rejection	↑
11-14-2005	Non-Final Rejection	
09-15-2005	Information Disclosure Statement considered	
08-29-2005	Information Disclosure Statement considered	
03-07-2005	Information Disclosure Statement considered	
10-27-2003	Information Disclosure Statement considered	
09-15-2005	Reference capture on IDS	
09-15-2005	Information Disclosure Statement (IDS) Filed	17
09-15-2005	Information Disclosure Statement (IDS) Filed	
08-29-2005	Information Disclosure Statement (IDS) Filed	↑
08-29-2005	Information Disclosure Statement (IDS) Filed	↑
09-07-2005	Date Forwarded to Examiner	↑
08-29-2005	Response to Election / Restriction Filed	↑
08-29-2005	Request for Extension of Time - Granted	
06-29-2005	Mail Restriction Requirement	184
06-27-2005	Requirement for Restriction / Election	↑
04-05-2005	Case Docketed to Examiner in GAU	↑
03-07-2005	Reference capture on IDS	↑
03-07-2005	Information Disclosure Statement (IDS) Filed	↑
03-07-2005	Information Disclosure Statement (IDS) Filed	↑
10-27-2003	Reference capture on IDS	↑
10-19-2004	IFW TSS Processing by Tech Center Complete	↑
10-27-2003	Information Disclosure Statement (IDS) Filed	↑
10-27-2003	Information Disclosure Statement (IDS) Filed	↑
10-19-2004	Case Docketed to Examiner in GAU	↑

02-05-2004	Application Return from OIPE	↑
02-05-2004	Application Return TO OIPE	↑
02-05-2004	Application Is Now Complete	↑
02-03-2004	Application Dispatched from OIPE	↑
02-04-2004	Application Is Now Complete	↑
01-28-2004	Cleared by L&R (LARS)	↑
01-20-2004	Referred to Level 2 (LARS) by OIPE CSR	↑
12-10-2003	IFW Scan & PACR Auto Security Review	↑
10-27-2003	Initial Exam Team nn	↑

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